EXHIBIT 1

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UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

University of Western Australia,
Junior Party
(Patents 7,960,541 and 7,807,816
Inventors: Stephen Donald Wilton, Sue Fletcher and Graham McClorey)

v.

Academisch Ziekenhuis Leiden,
Senior Party
(Application 13/550,210,
Inventor: Judith C. van Deutekom).

Patent Interference No. 106,008 (RES)
(Technology Center 1600)

Before: RICHARD E. SCHAFER, SALLY GARDNER LANE, and DEBORAH KATZ, *Administrative Patent Judges*

SCHAFER, *Administrative Patent Judge.*

Decision - Motions - 37 C.F.R. § 41.125(a)

This interference is between University of Western Australia (UWA) Patents 7,960,541 and 7,807,816 and Academisch Ziekenhuis Leiden (AZL) application 13/550,210.

The following motions are before us for consideration:

(1) UWA Motion 1 asserting certain AZL claims are unpatentable under 35 U.S.C. § 112(a) (Paper 213);

(2) UWA Motion 2 asserting certain AZL claims are unpatentable under 35 U.S.C. § 112(b) (Paper 214);

(3) UWA Motion 3 that AZL claims are barred under 35 U.S.C. § 135(b)(1) for failing to have been made within one year of the issuance of UWA's Patents (Paper 215);

(4) UWA Miscellaneous Motion 1 to file a terminal disclaimer (Paper 22);

(5) UWA Miscellaneous Motion 4 seeking to exclude certain of AZL's evidence (Paper 463);

(6) AZL Substantive Motion 1 asserting that UWA's claims are unpatentable over certain prior art under 35 U.S.C. §§ 102 and 103 (Paper 184);

(7) AZL Substantive Motion 2 to deny UWA the benefit of Australian Application 2004903474 (Paper 29);

(8) AZL Substantive Motion 3 asserting that certain UWA claims are unpatentable under 35 U.S.C. § 101 as interpreted by *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013) (Paper 30); and

(9) AZL Responsive Motion 4 to add two claims to correct the alleged unpatentability of AZL Claims asserted in UWA's Motions 1 and 2. (Paper 245).

The general subject matter

The subject matter claimed by the parties relates to "exon skipping." Exon skipping is a molecular biology technique that may be useful for ameliorating or eliminating the effects of certain genetic mutations. Those mutations may result in

a shift in the reading frame during protein formation resulting in a non-functional, or partially functional, protein. The exon skipping technique, in effect, hides certain pre-mRNA exons from the mRNA formation machinery. As a result, the hidden exon is removed along with introns during the splicing to form mRNA. The exon skipping is said to be caused by the binding of an oligonucleotide that includes a nucleobase sequence that is complementary to a portion of a particular pre-mRNA exon. The complimentary oligonucleotide is referred to as an antisense oligonucleotide or "AON." Both the exon to be discarded and the AON are chosen to restore an open reading frame allowing for the formation of a more complete and more functional protein.

Specifically, the parties' invention is directed to AONs selected to cause skipping of exon 51 of the pre-mRNA associated with the gene responsible for the formation of the protein dystrophin. The absence of dystrophin prevents skeletal muscle development and causes the myopathies of muscular dystrophy. In people suffering from Duchenne muscular dystrophy (DMD), the mutation in the dystrophin gene essentially precludes the formation of any functional dystrophin. By skipping, and thus removing, exon 51 during the formation of mRNA, a reading frame is said to be restored, resulting in the formation of a partially functional dystrophin protein.

UWA's Motion 3 – 35 U.S.C. § 135(b)(1)

The Board may take up motions for decision in any order. 37 C.F.R. § 41.125(a). Because a motion alleging that an opponent's claims were untimely made under 35 U.S.C. § 135(b)(1) raises a possible threshold issue, we address UWA's Motion 3 first. *See* 37 C.F.R. § 41.201, definition of threshold issue.

UWA moves for a judgment against AZL's involved claims asserting that they are barred under 35 U.S.C. § 135(b)(1) for failing to have been made within one year of the issuance of UWA's involved patents. UWA Motion 3, Paper 215.

AZL responds arguing that its current claims are supported by pre-critical date claims in its parent applications 12/198,007 and 11/233,495. AZL Opposition 3, Paper 397.

We grant UWA's motion.

AZL's involved claims

AZL's involved application includes Claims 11, 12, 14, 15, 17-29. Claims 11, 15, 19 and 26 are independent. Each of the claims is directed to AONs defined partially by structure and partially by function. We reproduce representative Claim 11 below, with paragraphing and bracketing added:

> 11. An isolated antisense oligonucleotide of 20 to 50 nucleotides in length, comprising
>
> a morpholino ring
>
> *[1]wherein said oligonucleotide is capable*
>
> *[a] of binding to an exon-internal sequence of exon 51 of the human dystrophin pre-mRNA and*
>
> *[b] inducing exon skipping,*
>
> *[2] wherein h51AON1 (UCAAGGAAGAUGGCAUUUCU) (SEQ ID NO: 27) is capable of binding to said exon-internal sequence.*

AZL Clean Copy of Claims, Paper 8, 1:3-7. The independent claims, and by incorporation-by-reference each of the dependent claims, include the limitations italicized above. h51AON1 is the designation given by AZL's inventors to a 20 nucleotide AON having the sequence of SEQ ID NO: 27. Ex. 1009, p. 44. It is said to be capable of causing exon skipping of exon 51 of human dystrophin pre-mRNA. *Id.*

AZL's claims require that the AONs satisfy two functional "capable of binding" limitations: (1) The AONs must be capable of binding to an exon-internal sequence of exon 51 of the pre-mRNA (limitation [1][a] above) and (2) the AON

designated as h51AON1 must be capable of binding to the same exon internal sequence to which the AON binds ([2] above). We shall refer to these two requirements as the "dual-binding limitation." In addition, the AONs encompassed by the claims must cause exon skipping ([1][b] above). We refer to this limitation as the "exon-skipping limitation."

Analysis

Under 35 U.S.C. § 135(b)(1) (pre-AIA) applicants are barred from obtaining claims to subject matter that is the same or substantially the same as subject matter claimed in a patent unless the applicant made those claims within one year of the issuance of the patent:

> A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

35 U.S.C. § 135(b)(1) (2010). The statute codifies a legal principal similar to laches by imposing what effectively is a statute of limitations on interferences to make a patentee more secure in the patent property right. *In re Berger*, 279 F.3d 975, 982 (Fed. Cir. 2002). Where an applicant makes a claim that is directed to the same or substantially the same subject matter as a patent claim more than a year after the patent issued, the applicant must show that it had support for the claimed subject matter in claims filed before the one-year critical date. *Regents of the Univ. of Cal. v. Univ. of Iowa Research Found.*, 455 F.3d 1371, 1374 (Fed.Cir.2006). The applicant must establish that the later filed claims do not differ from the pre-critical date claims in any material limitation. *Id.* The subject matter of multiple pre-critical date claims, taken together, may be relied upon to show that the subject matter of the pre-critical date claims does not differ materially from the subject matter of the post-critical date claims. *Pioneer Hibred Int'l, Inc. v. Monsanto Tech. LLC*, 671 F.3d 1324, 1330 (Fed. Cir. 2012). Those

earlier claims must demonstrate an intent to claim an invention including all the material limitations of the later filed claims. *Id*. However, a material limitation need not be explicitly expressed in the earlier claims so long as the material limitation is inherent, i.e., "necessarily results" from other limitations in the claim. *Berger*, 279 F.3d at 983. The fact that the material limitation is disclosed in the written description of a pre-critical date specification or drawing is not relevant. *See id*. ("As our precedent makes clear, '[t]he inquiry here is not whether such a step is inherently disclosed, as it might be in a right-to-make case. Rather, the question is whether the step necessarily occurs in the process as claimed.'").

One indicia of a material limitation is that the limitation was necessary for patentability. A limitation is presumed to be material if it was added in response to a rejection and resulted in allowance. *Adair v. Carter*, 668 F.3d 1334, 1339 (Fed. Cir. 2012) ("When an applicant adds limitations in response to an examiner's rejection, and those limitations result in allowance, there exists a well established presumption that those limitations are necessary to patentability and thus material.")

Relevant Dates

UWA's involved '541 patent issued on June 14, 2011. Ex. 1002, p. 1. UWA's involved '816 patent issued October 5, 2010. Ex. 1001, p. 1. Thus, the critical date for § 135(b)(1) purposes is October 5, 2011. 35 U.S.C. § 135(b)(1). AZL's involved application was filed on July 16, 2012. Ex. 1009, p. 1. AZL's involved claims were placed into their final and current form by an amendment filed on May 12, 2014. Ex. 2064, pp. 2-4; Ex. 2076, p. 4.

AZL does not argue that its involved claims and UWA's involved claims are not directed to the same or substantially the same subject matter. Thus, at least facially, AZL's claims were "made" after the critical date.

Materiality.

UWA says the following, present in all of AZL's claims, are material limitations:

> wherein said oligonucleotide is capable of binding to an exon-internal sequence of exon 51 of the human dystrophin pre-mRNA and inducing skipping of exon 51 and wherein h51A0N1 (UCAAGGAAGAUGGCAUUUCU) (SEQ ID NO: 27) is capable of binding to said exon-internal sequence.

UWA Motion 3, Paper 215, 5:5 – 6:5. These are the dual-binding and exon-skipping limitations we identified above. The limitations were first added to AZL's involved application, subsequent to the critical date, by the amendment of May 12, 2014. Ex. 2064.

In UWA's view, the limitations are material because they were added to overcome the examiner's rejections of the claims and are therefore "necessary to patentability." "When an applicant adds limitations in response to an examiner's rejection, and those limitations result in allowance, there exists a well established presumption that those limitations are necessary to patentability and thus material." *Adair*, 668 F.3d at 1339 (*citing Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002)). *See also*, *Parks v. Fine*, 773 F.2d 1577, 1579 (Fed. Cir. 1985) ("The insertion of this limitation to overcome the examiner's rejection is strong, if not conclusive, evidence of materiality.")

We turn to the prosecution of AZL's involved claims to determine whether the identified limitations were necessary to patentability and thus should be presumptively considered material. As we noted above, both the dual-binding limitation and the exon skipping limitation are present in all of AZL's involved claims. AZL Clean Copy of Claims, Paper 8. The limitations were added to independent Claims 11, 15 and 19 by the amendment of May 12, 2014. Ex. 2064. Independent Claim 26, which was newly added by the same amendment also

included both limitations. Ex. 2064, p. 4. We will focus on the prosecution of AZL Claim 11 as representative of the prosecution of AZL's involved claims.

At the time the examiner first considered AZL's '210 application, it included 16 claims, 1-16.[1] Ex. 2062, pp. 2-3. Claim 11 stated:

> 11. (New) An isolated antisense oligonucleotide of 20 to 50 nucleotides in length,
>
> said oligonucleotide comprising a sequence which is complementary to a target nucleic acid sequence of exon 51 of the human dystrophin pre-mRNA,
>
> wherein the target nucleic acid sequence comprises a nucleotide sequence that is complementary to the sequence UCAAGGAAGAUGGCAUUUCU (SEQ ID NO: 27).

Ex. 2062, p. 3. The claim does not include the dual-binding and exon-skipping limitations.

Claim 11 as well as the other claims were rejected on a variety of different grounds including : (1) obviousness (Claims 1-16); (2) anticipation (Claims 1, 2, 6. 7, 8-12 and 16) (3) double patenting (Claims 1-16); indefiniteness (Claims 1-10), (4) lack of written description (Claims 6 and 16). Ex. 2080, pp. 2-11. In response to the rejection, on January 21, 2014, AZL filed an amendment, cancelling claims 1-10, 13 and 16, amending Claims 11, 12, 14 and 15, and adding Claims 17-25. Ex. 1052, pp. 2-3. On May 9, 2014, before the examiner acted on the amendment, AZL's counsel had an interview with the examiner. Ex. 2076, p. 2. During the interview, the examiner indicated that the amended claims filed January 21, 2014, were unpatentable because they introduced new matter. *Id.* However, the examiner also indicated that proposed amended claims

[1] The '210 application is said to be a continuation of Application 12/976,381. As originally filed, the '210 specification included 3 claims. Those claims were replaced in a pre-amendment with claims 1-10. A subsequent pre-amendment, filed before the examiner considered the application, amended dependent claims 2-10 and added Claims 11-16. Ex. 2062, pp. 2-3.

presented during the interview would be allowable. *Id.* Following the interview, on May 12, 2014, AZL filed a supplemental amendment apparently in conformity with the claims discussed during the interview. Ex. 2064. The supplemental amendment further amended Claims 11, 12, 15, 17-19 and 23-25 and added Claims 26-29, bringing the claims to their present allowable form. Ex. 2064, pp. 2-4; Ex. 2076, p. 4. For the first time, the claims included the dual-binding and exon-skipping limitation. Ex. 2064, *id.* The examiner determined that those claims were patentable, but for the outcome of the interference, and suggested that an interference be declared with UWA's patents. Ex. 2076, p. 4.

In the table below we compare Claim 11 as originally presented in the '210 application with the allowed version with differences shown italicized:

Claim 11 as originally added by the amendment of January 13, 2013. Ex. 2062, p. 3.	Claim 11 from the amendment of May 12, 2014, and as allowed by the Examiner. Ex. 2064, p. 2.
11. (Original) An isolated antisense oligonucleotide of 20 to 50 nucleotides in length, said oligonucleotide comprising *a sequence which is complementary to a target nucleic acid sequence of exon 51 of the human dystrophin pre-mRNA*, *wherein the target nucleic acid sequence comprises a nucleotide sequence that is complementary to the sequence* UCAAGGAAGAUGGCAUUUCU (SEQ ID NO: 27).	11. (As allowed) An isolated antisense oligonucleotide of 20 to 50 nucleotides in length, comprising *a morpholino ring*[2] *wherein said oligonucleotide is cable of binding to an exon-internal sequence* of exon 51 of the human dystrophin pre-mRNA and *inducing exon skipping*, *wherein* h51AON1 (UCAAGGAAGAUGGCAUUUCU) (SEQ ID NO: 27) *is capable of binding to said exon internal sequence.*

[2] The "morpholino ring" serves as the backbone of the AON. Each of AZL's independent claims recite a different backbone. The recitation of the specific backbone has not been asserted to be a material difference between the pre-and post-critical date claims.

We find from the above-described prosecution history that the claims were not considered allowable until AZL added the functional dual-binding and exon skipping limitations to overcome the examiner's objections. AZL does not argue to the contrary. The dual-binding limitations and the "capable of inducing exon skipping" are, therefore, presumptively material. *Adair*, 668 F.3d at 1339.

Pre-critical date support

AZL argues that the limitations are supported by pre-critical date claims in its '007 and '495 applications.

Burden of Proof on pre-critical date support

AZL argues that it is UWA's burden to demonstrate "that each of AZL's post-critical date claims contains material limitations which were not explicitly or inherently present in AZL's pre-critical date claims." AZL Opposition 3, Paper 397, 5:10-12.

AZL is incorrect. While the overall and ultimate burden of persuasion with respect to UWA Motion 3, is and remains with UWA (37 C.F.R. § 41.121(b)), the initial burden is met when the motion is supported by appropriate evidence that, if unrebutted, would justify the relief sought. 37 C.F.R. § 41.208(b). Here the evidence shows that the subject matter of AZL's involved claims was first made after the critical date. UWA has also identified material limitations and explained why those claims are material. UWA Motion 3, Paper 215, 5:5 – 6:5. AZL has not contested that its involved claims are directed to the same or substantially the same subject matter as UWA's claims. Where it has been established that the subject matter of the applicant's claims was first made after the critical date, the opponent must show that its post-critical date claims are "not materially different from a pre-critical date claim present in the application or any predecessor thereto in order to obtain the benefit of the earlier filing date . . . ." *Adair*, 668 F.3d at 1339. In other words, while UWA bears and maintains the overall burden of

persuasion with respect to the motion and the bar under 35 U.S.C. § 135(b)(1), AZL bears the burden of persuasion on the issue of pre-critical date support for the post-critical date claims: "To establish entitlement to the earlier effective date of existing claims for purposes of the one-year bar of 35 U.S.C. § 135(b), a party *must show* that the later filed claim does not differ from an earlier claim in any 'material limitation.' " *In re Berger*, 279 F.3d at 981–82 (Fed. Cir. 2002) *quoting Corbett v. Chisholm, 568 F.2d 759, 765–66 (CCPA 1977) (emphasis added.).*

Application 12/198,007

AZL argues that Claim 20 of its involved application is supported by pre-critical date Claims 1 and 2 of its grand-parent '007 application. AZL Opposition 3, 19-23. Claim 20 depends from independent Claim 19. Claim 19 and, thus, Claim 20 each require the presumptively material dual-binding limitation as well as the exon-skipping limitation. Claim 2 of the '700 application depends from Claim 1. We present a side-by-side comparison of the pre- and post-critical claims below with the differences in subject matter italicized:

Pre-critical date claims from Application 12/198,007. Ex. 2067, p. 2.	Post-critical date claims from involved Application 13/550,210. AZL Clean Copy of Claims, Paper 8, 1:22 – 2:4.
1. An isolated oligonucleotide of between 20 to 50 nucleotides comprising a sequence *consisting of* SEQ ID: 27.	19. An isolated *antisense* oligonucleotide of 20 to 50 nucleotides in length, comprising a 2'-O-methyl ribose moiety, *[1]wherein said oligonucleotide is cable* *[a] of binding to an exon-internal sequence of exon 51 of the hu man dystrophin pre-mRNA and* *[b] inducing exon skipping,* *[2] wherein h51AON1 (UCAAGGAAGAUGGCAUU UCU) (SEQ ID NO: 27) is capable of binding to said exon internal sequence. SEQ ID NO: 27) is capable of binding to said exon-internal sequence.*
2. The isolated oligonucleotide of claim 1, wherein the oligonucleotide comprises a 2'-O-methyl-phosphorothioate oligoribonucleotide modification"	20. The oligonucleotide of claim 19, further comprising a phosphorothioate internucleoside linkage.

According to AZL, one skilled in the art would not consider the differences between the pre and post-critical claims to be material. AZL Opposition 3, Paper 397, 19: 3 – 23:12. The effect of the limitations, says AZL, is merely to narrow the scope of the claims to include only AONs that cause exon-skipping: AZL Opposition 3, Paper 397, 22:16 – 23:2. AZL directs us to the testimony of Dr. Erik Sontheimer for support. *Id.* He testifies that

> a person of skill in the art would understand that the combined function of these three limitations is to narrow the scope of [the claims of the involved application] to include only oligonucleotides which cause exon-skipping, thus excluding the small fraction of inoperative oligonucleotides from what was covered in the pre-critical date claims.

Ex. 1186, ¶ 81, 23:22-25.

We simply do not see the relevance of this argument to whether the amendments added material limitations. We fail to see why, under the facts of the prosecution of the AZL's involved application, narrowing the scope of the claims in response to the examiner's rejections, and thereby putting the claims in condition for allowance, was not necessary to patentability. Indeed, such an amendment would seem to be an example of a limitation "necessary to patentability." *See Adair*, 668 F.3d at 1339 (Fed. Cir. 2012) ("When an applicant adds limitations in response to an examiner's rejection, and those limitations result in allowance, there exists a well established presumption that those limitations are necessary to patentability and thus material."). Dr. Southeimer does not explain why one skilled in the art would consider a limitation that narrowed the scope of the claims in response to the examiner's rejections and overcame the Examiner's rejections would not be considered "necessary to patentability" and, therefore, not a material limitation.

Additionally, we do not credit Dr. Sontheimer's testimony that the effect of the added limitations was simply to eliminate inoperative/non-skip-causing species. Ex. 1186, ¶¶ 70-81. Eliminating the inoperative species could have been accomplished simply by requiring that the oliognucleotide induce exon skipping. However, the addition of the dual-binding limitation significantly broadened the claim scope to include AONs having sequences that are not included in the cited pre-critical date claims. AZL directs us to Claims 1 and 2 from its

'007 Application. AZL Opposition 3, Paper 397, 20:9-28. In relevant part those Claims 1 and 2 of the '007 application require:

> "An isolated oligonucleotide of between 20 to 50 nucleotides comprising a sequence consisting of SEQ ID: 27."

AZL Opposition 3, Paper 397, 20:21-23. The AONs covered by those claims must "comprise," and therefore must include, the complete set of the twenty nucleotides of SEQ ID: 27 (h51AON1), but do not require inducing exon skipping. All of AZL's involved claims, while narrower than its earlier claims in requiring inducing exon skipping, are broader in not requiring all 20 nucleotides of h51AON1 to be present in the covered AONs. All that is required is the AON include some unspecified number of the nucleotides of h51AON1 sufficient to be "capable of binding" to the same "exon internal sequence" to which the AON binds. Dr. Sontheimer's testimony to the effect that the differences between the pre- and post-critical date claims was simply narrowing the scope of the claims is inconsistent with the broadened language of AZL's involved claims. His testimony is also conclusory in that he does not provide an explanation why one skilled in the art would understand the limitations to simply "exclude the small fraction of inoperative oligonucleotides." We therefore do no credit his testimony on this point.

AZL has not established that the differences between Claims 1 and 2 of its pre-critical date '007 application and its involved claims are not material differences.

Application 11/233,495

AZL also directs us to a combination of the subject matter of claims 15, 26 and 70, as filed on July 26, 2011, in its '495 application as pre-critical date support for its involved claims. AZL argues that the material limitations are explicit or

inherent in those claims. AZL Opposition 3, Paper 397, 6:10 – 9:16. We reproduce these claims below with paragraphing added:

> 15. An oligonucleotide or an equivalent thereof produced by a method comprising:
>
> (a) determining from a secondary structure of a premRNA from an exon, regions that assume a structure that is hybridized to part of said pre-mRNA (closed structure) and regions that are not hybridized in the structure (open structure), wherein the gene from which said pre-mRNA comprising said exon is transcribed is an aberrant human dystrophin gene,
>
> wherein said exon comprises an exon selected from the group consisting of human exons 2, 8, 9, 17, 19, 29, 40, 41, 42, 43, 44, 45, 46, 49, 50, 51, 52, 53, 55 and 59;
>
> (b) designing an oligonucleotide or equivalent thereof comprising a structure of which at least a part is complementary to said closed structure and of which at least another part is complementary to said open structure,
>
> wherein binding of said oligonucleotide or the equivalent thereof comprising said structure to said pre-mRNA alters the splicing of said pre-mRNA, and
>
> wherein said designing is based on the results of said determining step; and
>
> (c) generating the oligonucleotide or the equivalent thereof of step (b).
>
> 26. A method of inducing exon skipping in a premRNA, said method comprising:
>
> providing the oligonucleotide or the equivalent thereof according to claim 15; and
>
> inducing exon skipping in a pre-mRNA.
>
> 70. An oligonucleotide or equivalent thereof produced by a method comprising:
>
> (a) determining from a secondary structure of a premRNA from an exon, regions that assume a structure that is hybridized to part of said pre-mRNA (closed structure) and regions that are not hybridized in the structure (open structure),

> wherein the gene from which said pre-mRNA comprising said exon is transcribed is an aberrant human dystrophin gene;
>
> (b) designing an oligonucleotide or equivalent thereof comprising a structure of which at least a part is complementary to said closed structure and of which at least another part is complementary to said open structure, wherein said oligonucleotide is of between 14 and 50 nucleotides and comprising a DNA or RNA sequence of an oligonucleotide selected from the group consisting of: h2AON1 (SEQ ID NO: 1), h29AON1 (SEQ ID NO: 3), h29AON2 (SEQ ID NO: 4), h40AON1 (SEQ ID NO: 5), h40AON2 (SEQ ID NO: 6), h41AON1 (SEQ ID NO: 7),h41AON2 (SEQ ID NO: 8), h42AON1 (SEQ ID NO: 9), h42AON2 (SEQ ID NO: 10), h43AON2 (SEQ ID NO: 12), h44AON1 (SEQ ID NO: 13), h44AON2 (SEQ ID NO: 14), h45AON5 (SEQ ID NO: 16), h46AON 4b (SEQ ID NO: 17), h46AON 8b (SEQ ID NO: 18), h49AON1 (SEQ ID NO: 23), h49AON2 (SEQ ID NO: 24), h50AON1 (SEQ ID NO: 25), h51AON1 (SEQ ID NO: 27), h51AON2 (SEQ ID NO: 28) or h53AON1 (SEQ ID NO: 29);
>
> wherein binding of said oligonucleotide or the equivalent thereof comprising said structure to said pre-mRNA alters the splicing of said pre-mRNA, and
>
> wherein said designing is based on the results of said determining step; and
>
> (c) generating the oligonucleotide or the equivalent thereof of step (b).

Claims of Application 11/233,495, Ex. 1222, pp. 2, 4, 9-10

We held above that AZL's dual-binding limitation was presumptively material. Assuming, without deciding, that the subject matters of AZL Claims 15, 26 and 70 of the '495 application are sufficiently related to be combined for the purposes of § 135(b)(1), we are not convinced that the dual-binding concept is either explicitly present or is inherent in the subject matter of those claims.

Claims 15, 26 and 70 are product by process claims. Central to the subject matter of those claims is the process of designing an AON that is at least partially

complementary to the open and closed secondary structure of a number of exons including exon 51. AZL's involved claims do not include the process of utilizing the exon secondary structure to identify, determine and design the appropriate AONs. AZL Clean Copy of Claims, Paper 8. In addition to the steps of determining, designing and generating certain AONs, Claim 70 adds that the AONs must include the sequence of one of a number of AONs including h51AON. That AON includes the full twenty nucleotide sequence identified as SEQ ID NO:27. Claims 15 and 70 further specify that binding of the AONs alters the splicing of the pre-mRNA. Claim 26 is directed to the method of inducing exon skipping by "providing" the AON of Claim 15.

A comparison of Claim 15, 26 and 70 of the '495 application and AZL's involved claims shows that the latter claims express and encompass a concept and subject matter not present in the pre-critical date claims. AZL's current claims require the dual-binding limitation. This, in our view, is a significantly different and broader concept than that conveyed by an AON that must include the twenty nucleotide sequence of h51AON1 encompassed by Claim 70 or the aggregate of that claim with Claims 15 and 26 of the '495 application. AZL has not explained where those claims, either alone or in aggregate, explicitly express the dual-binding concept that the AON must be capable of binding to an exon internal sequence and the h51AON must be able to bind to that same sequence.

AZL also argues that the dual-binding limitation is inherent in the '495 application claims. AZL Opposition 3, Paper 397, 6:17 – 9:16. In order to show that the material limitations are inherent in the earlier claims, it must be shown that those limitations are necessarily present in the earlier claims. *Berger*, 279 F.3d at 983. In other words, the material limitations of AZL's involved claims must necessarily result from the limitations of Claims 15, 26 and 70 of the '495 application. AZL's involved claims require the dual-binding limitation.

We are not convinced that these limitations necessarily result from AZL's earlier claims. The combination of Claims 15, 26 and 70 of the '495 application reasonably show an intent to claim AONs, that bind to exon 51 (Claim 15), that include the complete 20 nucleotide sequence of h51AON1 (SEQ ID NO:27) (Claim 70), and that induce exon skipping (Claim 26). However, the dual-binding limitation present in all of AZL's involved claims embodies a significantly different and broader concept. Those claims include AONs that are capable of binding to an exon-internal sequence of exon 51 but need only have sufficient nucleotide similarity with an unspecified number of the twenty nucleotides of h51AON1 such that h51AON1 is also capable of binding to the same exon-internal sequence to which the AON binds. Unlike the pre-critical date claims, the AONs of the involved claims do not require that the complete twenty nucleotide sequence of h51AON1 be present in the AONs.

With respect to the dual-binding concept, AZL argues:

> A person of skill in the art would immediately understand, based on the known sequence of exon 51, the sequence specified in SEQ ID NO: 27, and the rules of Watson-Crick base pairing, that h51AON1 (SEQ ID NO: 27) inherently binds to the sequence 5'-AGAAAUGCCAUCUUCCUUGA-3' on the pre-mRNA of exon 51.

AZL Opposition 3, Paper 397, 9:6-9. We do not disagree with this statement. However, AZL has not explained why its broader dual-binding limitation necessarily flows from the fact that the h51AON1 binds with its complementary pre-mRNA.

AZL also argues that

> every oligonucleotide defined by the aggregate of pre-critical date claims 70, 15 and 26, which must include h51AON1 (SEQ ID NO: 27) as part of its sequence, would inherently satisfy the

> limitation that "h51AON1 (UCAAGGAAGAUGGCAUUUCU) (SEQ ID NO: 27) is capable of binding to said exon-internal sequence.

AZL Opposition 3, Paper 397, 9:12-15. In other words, with respect to h51AON1 the subject matter of AZL's involved claims is said to be generic to the aggregated subject matter of pre-critical date claims 15, 25 and 70. While we agree that h51AON1 would likely meet the dual-binding and exon-skipping limitations, we fail to see how those claims necessarily include and convey possession of the dual-binding concept. As noted above, there is a difference in scope with respect to the AONs encompassed by the involved claims and those AONs that must include the complete twenty nucleotide sequence of h51AON1 of the pre-critical date claims. AZL has not adequately explained why this difference in scope between the h51AON1 containing AONs of, for example, Claim 70 of the '495 application, and the broader scope of AZL's involved claims does not constitute a material difference.

We are not convinced that AZL has shown that the dual-binding limitation is supported by Claims 15, 26 and 70 of AZL's '495 application.

Conclusion

We grant UWA's Motion 3.

As a result of the decision granting UWA's Motion 3, all of AZL's claims are barred under 35 U.S.C. § 135(b)(1). The absence of an interfering claim that is not barred under § 135(b) renders an interference nonexistent, and thus deprives the Board of its authority to continue the proceeding. *Berman v. Housey*, 291 F.3d 1345 (Fed. Cir. 2002). *See also*, *Parks v. Fine*, 773 F.2d 1577, 1581 (Fed.Cir.1985) (vacating the Board's award of priority because Fine's claims were barred under § 135(b), and concluding that "[t]he interference being dissolved,

there is no occasion to award priority to either party").[3] Accordingly, we do not reach the other motions and a judgment will be issued against AZL in a separate paper.

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[3] Beginning with the 1984 revision of the interference rules, interferences were no longer "dissolved." Instead, accept under very rare circumstances, interferences are terminated with a judgment. See Final Rule, Patent Interference Proceedings, 49 Fed. Reg. 48416, 48447 (December 12, 1984) ("[A]ll interferences will be terminated with a 'judgment.'")